

LEVOCETIRIZINE DIHYDROCHLORIDE- levocetirizine dihydrochloride tablet, coated
CVS PHARMACY

Drug Facts

Active ingredient (in each tablet)

Levocetirizine dihydrochloride USP, 5 mg

Purpose

Antihistamine

Uses

temporarily relieves these symptoms due to hay fever or other respiratory allergies:

- runny nose
- sneezing
- itchy, watery eyes
- itching of the nose or throat

Warnings

Do not use

- if you have kidney disease
- if you have ever had an allergic reaction to this product or any of its ingredients or to an antihistamine containing cetirizine

Ask a doctor before use if you have

- ever had trouble urinating or emptying your bladder

When using this product

- drowsiness may occur
- avoid alcoholic drinks
- alcohol, sedatives, and tranquilizers may increase drowsiness
- be careful when driving a motor vehicle or operating machinery

Stop use and ask doctor if

- you have trouble urinating or emptying your bladder
- an allergic reaction to this product occurs. Seek medical help right away.

If pregnant or breast-feeding:

- if breast-feeding: not recommended

- if pregnant: ask a health professional before use

Keep out of reach of children

In case of overdose, get medical help or contact a Poison Control Center right away (1-800-222-1222).

Directions

adults 65 years of age and older	<ul style="list-style-type: none"> • ask a doctor
adults and children 12-64 years of age	<ul style="list-style-type: none"> • take 1 tablet (5 mg) once daily in the evening • do not take more than 1 tablet (5 mg) in 24 hours • 1/2 tablet (2.5 mg) once daily in the evening may be appropriate for less severe symptoms
children 6-11 years of age	<ul style="list-style-type: none"> • take 1/2 tablet (2.5 mg) once daily in the evening • do not take more than 1/2 tablet (2.5 mg) in 24 hours
children under 6 years of age	<ul style="list-style-type: none"> • do not use
consumers with kidney disease	<ul style="list-style-type: none"> • do not use

Other information

- store between 20° and 25°C (68° and 77°F)
- (bottle only) safety sealed: do not use if carton was opened or if printed foil inner seal on bottle is torn or missing
- (blisters only) safety sealed: do not use if seal is broken or if individual blister unit is open or torn

Inactive ingredients

colloidal silicon dioxide, hypromellose, lactose monohydrate, magnesium stearate, microcrystalline cellulose, polyethylene glycol, titanium dioxide

Questions or comments?

Call **1-888-375-3784**

Carton Label

CVS Health

Compare to the active ingredient
in Xyzal® Allergy 24HR*

Original Prescription Strength
Allergy Relief
Levocetirizine Dihydrochloride
Tablets USP, 5 mg
Antihistamine

24 HOUR

24 Hour Relief of:

- Sneezing
- Runny nose
- Itchy nose or throat
- Itchy, watery eyes

35 TABLETS Actual bottle size on side panel



Bottle Label

CVS
Health

Original Prescription Strength

Allergy Relief
Levocetirizine
Dihydrochloride
Tablets USP, 5 mg
Antihistamine

35 TABLETS 24 HOUR

CVS Health.

Original Prescription Strength Allergy Relief
LEVOCETIRIZINE DIHYDROCHLORIDE TABLETS USP, 5 mg
Antihistamine

35 TABLETS

Active ingredient (in each tablet)
 Levocetirizine dihydrochloride USP, 5 mg.....**Purpose**
 Antihistamine

Uses temporarily relieves these symptoms due to hay fever or other respiratory allergies: ■ runny nose ■ sneezing ■ itchy, watery eyes ■ itching of the nose or throat **Warnings** Do not use ■ if you have kidney disease ■ if you have ever had an allergic reaction to this product or any of its ingredients or to an antihistamine containing cetirizine Ask a doctor before use if you have ■ ever had trouble urinating or emptying your bladder When using this product ■ drowsiness may occur ■ avoid alcoholic drinks ■ alcohol, sedatives, and tranquilizers may increase drowsiness ■ be careful when driving a motor vehicle or operating machinery Stop use and ask a doctor if ■ you have trouble urinating or emptying your bladder ■ an allergic reaction to this product occurs. Seek medical help right away. If pregnant or breast-feeding: ■ if breast-feeding: not recommended ■ if pregnant: ask a health professional before use

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Peel Here ↑

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LEVOCETIRIZINE DIHYDROCHLORIDE

levocetirizine dihydrochloride tablet, coated

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:69842-761(NDC:43598-735)
Route of Administration	ORAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
levocetirizine dihydrochloride (UNII: SOD6A38AGA) (levocetirizine - UNII:6U5EA9RT2O)	levocetirizine dihydrochloride	5 mg

Inactive Ingredients

Ingredient Name	Strength
CELLULOSE, MICROCRYSTALLINE (UNII: OP1R32D61U)	
LACTOSE MONOHYDRATE (UNII: EWQ57Q8I5X)	
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
MAGNESIUM STEARATE (UNII: 70097M6I30)	

HYPROMELLOSES (UNII: 3NXW29V3WO)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	
Polyethylene Glycol, Unspecified (UNII: 3WJQ0SDW1A)	

Product Characteristics			
Color	white	Score	2 pieces
Shape	OVAL	Size	9mm
Flavor		Imprint Code	L
Contains			

Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:69842-761-35	1 in 1 CARTON	04/15/2018	
1		35 in 1 BOTTLE; Type 0: Not a Combination Product		
2	NDC:69842-761-80	1 in 1 CARTON	04/15/2018	
2		80 in 1 BOTTLE; Type 0: Not a Combination Product		
3	NDC:69842-761-10	2 in 1 CARTON	12/31/2018	
3		5 in 1 BLISTER PACK; Type 0: Not a Combination Product		
4	NDC:69842-761-55	1 in 1 CARTON	11/30/2022	
4		55 in 1 BOTTLE; Type 0: Not a Combination Product		

Marketing Information			
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
ANDA	ANDA210375	04/15/2018	

Labeler - CVS PHARMACY (062312574)